

## **REMARKS**

Claims 33-36, 46, 49, 51-53, 56, 59-73 are currently pending. Claims 1-32, 37-45, 47, 48, 50, 54, 55, 57 and 58 were previously cancelled. Claims 60-73 are currently withdrawn as directed to a non-elected invention. Claim 33 is currently amended and support can be found, for example, in the specification at column 3, lines 51-52, column 6, lines 53-55, and Figures 1 and 8. No new matter is added.

### **35 U.S.C. 112, 1<sup>st</sup> Paragraph Rejection**

Claim 34 stands rejected under 35 USC 112, 1<sup>st</sup> paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner objects to the description of “annular” surfaces. According to the Examiner’s definition, “annular” means “of, relating to, or forming a ring.” The Examiner states that a “ring” is “a circular band for holding connecting, hanging, pulling, packing, or sealing” and a “band” is “a strip serving to join or hold things together”. Applicants disagree with these definitions in the context of this invention. The ordinary meaning of annular is ring-shaped, thus a cylindrical tube with a lumen as disclosed clearly has an inner annular surface and outer annular surface. Applicants respectfully submit there is adequate support for this limitation.

### **35 U.S.C. 103(a) Rejections**

Claims 33-36, 46, 49, 51-53, 56 and 59 stand rejected under 35 U.S.C. 103(a) as being allegedly anticipated by U.S. Patent 5,122,154 to Rhodes (“Rhodes”) in view of U.S. Patent No. 5,957,971 to Schwartz (“Schwartz”). Rhodes describes an endovascular bypass graft 20 that includes a sleeve member 28 and spaced stent members 30.

Rhodes fails to disclose or suggest an elongated continuous cylindrical hollow structure having a lining, as recited by claim 33. The Examiner interprets the “elongated hollow structure” claimed as the stent members 30 of Rhodes. However, the stent members 30 do not form an *elongated continuous* structure, but rather are separate and distinct, narrow “ring-like” structures disposed on the sleeve 28, as shown in Figs. 1 and 8. Contrary to the Examiner’s definition of elongated as “stretched out,” elongated has a definition of “having more length than

width.”<sup>1</sup> The spaced stent members 30 of Rhodes are thus not elongated. Furthermore, it would go against the teaching of Rhodes to make the stent members elongated and continuous, since “the graft portions between the stents enable the stent to bend or flex thereat so that the graft can assume an arcuate, undulating or otherwise bent shape” (col 7, lines 46-50). Rhodes states that “since the stents are spaced apart and *do not extend continuously* along the length of the graft 20 the graft can be easily sized to whatever length vascular segment is desired” (col 7, lines 51-54, emphasis added). Thus, Rhodes fails to disclose an elongated continuous cylindrical hollow structure having a lining, as claimed.

Rhodes also fails to disclose or suggest a lining containing a plurality of through holes, as recited by claim 33. The Examiner asserts that the sleeve 28 “inherently contains a plurality of through holes” since it “may comprise...Dacron mesh (*ibid.*: column 7, line 33)” (Office Action, page 3). Rhodes states that “the graft 20 may include a thin layer of Dacron mesh (not shown) on the outer surface of the graft to impact into the vessel wall”(column 7, lines 32-35). Thus, the sleeve 28 is not *made of* Dacron mesh, but rather a mesh may be *attached onto* the outer surface of the sleeve. The Examiner states that the “Dacron mesh may be viewed as part of the Rhodes lining so as to define a composite” (Office Action, page 5). However, the through holes claimed extend through the entire thickness of the lining, not through part of the lining. Claim 33 has been amended for clarification. Thus, Rhodes fails to disclose any through holes in the sleeve 28.

The Examiner states that ePTFE inherently has a plurality of tortuous through holes, relying on Gore (3,953,566) in support of this assertion. Although Gore does describe manufacture of a tetrafluoroethylene polymer in a porous form, all forms of PTFE are not porous. According to MPEP 2112, “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic...In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” Therefore, the PTFE in Rhodes does not necessarily contain a plurality of through holes.

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<sup>1</sup> “elongated.” *The American Heritage® Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Company, 2004. 15 Jun. 2009. <Dictionary.com <http://dictionary.reference.com/browse/elongated>>.

Furthermore, one of ordinary skill in the art would not be motivated to use a porous form of PTFE in the sleeve of Rhodes, since Rhodes is concerned with tissue ingrowth and wants the sleeve to be impervious to tissue growth. Rhodes teaches away from prior art devices that are “mesh-like or otherwise open or perforated and hence susceptible to scar tissue ingrowth” (col 2, lines 65-67). The Examiner states that “[t]issue ingrowth not extending into the interior of the graft...does not imply that water molecules (or ions) and drug molecules (typically much smaller than tissue cells) are unable to pass through these through holes or pores.” (Office Action, page 5). However, there is no disclosure, teaching or suggestion in Rhodes to provide any holes or pores in the sleeve, and the Examiner is basing this rejection merely on hindsight reasoning.

Rhodes fails to disclose or suggest a lining comprising a polymer interfaced with a medication for delivery to a patient, as recited by claim 33. The Examiner interprets the “lining” claimed as the sleeve 28 of Rhodes. The Examiner admits that “Rhodes lacks mention of medications incorporated into the lining” (Office Action, page 3). Thus, sleeve 28 is not “interfaced with a medication for delivery to the patient.” The Examiner attempts to use Schwartz to cure this deficiency as discussed below.

As discussed above, Rhodes does not disclose all the limitations of claim 33, and Schwartz does not cure these deficiencies. Schwartz describes an intraluminal stent with a fibrin film coating thereon. However, Schwartz fails to disclose a lining containing a plurality of through holes, as the Examiner admitted in the interview of August 14, 2008. Thus, neither of the cited references disclose or suggest “a lining containing a plurality of through holes” as claimed. Furthermore, although Schwartz may disclose that a therapeutic can be incorporated into a fibrin film, this does not provide any teaching or suggestion for adding a therapeutic to the impervious ePTFE sleeve of Rhodes. An impervious sleeve cannot be considered to be equivalent to a fibrin film.

For at least the above reasons, Applicant respectfully requests withdrawal of the above rejections.

**CONCLUSION**

The Applicant respectfully submits that this application is now in condition for allowance. Should any questions arise, the Examiner is invited to contact the undersigned at the number given below. Applicant's representative hereby requests an interview with the Examiner and will call to ascertain a date and time convenient to the Examiner's schedule. The Commissioner is authorized to charge any additional necessary fees or to credit any overpayments to Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON LLP

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/Jocelyn D. Ram/  
Jocelyn D. Ram  
Registration No. 54,898

KENYON & KENYON LLP  
1500 K Street, N.W., Suite 700  
Washington, D.C. 20005-1257  
Tel: 202-220-4200  
Fax: 202-220-4201